K033305

OCT 31 2003

Special 510(k): Device Modification
INFINITY MultiView WorkStation TruST

---

1. 510(k) SUMMARY

as required per 807.92(c)

Submitters Name, Address:

Draeger Medical Systems, Inc.
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Establishment Registration Number: 1220063
Official Correspondent: Connie Hertel, Director, QA/RA
Contact person for this submission: Penelope H. Greco
Date submission was prepared: October 13, 2003

Trade Name, Common Name and Classification Name:

A. Trade Name:
INFINITY MultiView WorkStation

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Product Code	Class	Regulation Number
Detector and Alarm, Arrhythmia	MHX	III	870.1025
System, Network and Communication, Physiological Monitors	MSX	II	870.2300

Legally Marketed Device Identification:

K030738 Infinity MultiView WorkStation Telemetry with TruST
K023569 Infinity MultiView WorkStation VF3 Modifications
K980625 Infinity MultiView WorkStation Enhanced with Rest ECG

Device Description:

With the release of software version VF4, the Infinity MultiView WorkStation can receive ECG data sent from a Reynolds CardioCollect and process Rest ECG reports (K980625) when a CardioCollect is interfaced to a MultiView WorkStation via an RS232 connection. Additionally, when a 12-lead Rest ECG for a TruST monitored patient is successfully acquired and uploaded, the MultiView WorkStation calculates a set of baseline coefficients specific to each patient.

K033305

Special 510(k): Device Modification
INFINITY MultiView WorkStation TruST

The Indications for Use and Intended Use of the INFINITY MultiView WorkStation and Telemetry System have not changed with VF4 software. Testing has been performed in accordance with internal design control procedures and indicates no affect on the safety or efficacy of the MultiView WorkStation.

Intended Use:
The INFINITY MultiView WorkStation, INFINITY Network and Remote Display are indicated for use as a central monitoring device, communications network, and remote display for Draeger Patient Monitoring Systems and recorders.

The INFINITY MultiView WorkStation (MVWS) Telemetry System is intended to measure and produce visual and audible alarms for one or more physiological parameters

The INFINITY MultiView WorkStation with Rest ECG can provide interpretive diagnostic statements and reports when connected to a monitor with ECG monitoring capability.

The INFINITY MVWS telemetry System with TruST is intended for 12-Lead ECG monitoring with a reduced set of electrodes. Reconstructed leads are intended for real-time assessment of ST segment changes.

This device is intended for use in an environment where patient care is provided by Healthcare Professionals, i.e. Physicians, Nurses, and Technicians, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

Assessment of non-clinical performance data for equivalence: Section J

Assessment of clinical performance data for equivalence: Section J

Biocompatability: Not applicable

Sterilization: Not applicable

Standards and Guidances: Section J

Draeger Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 1 2003

Draeger Medical Systems, Inc.
c/o Ms. Penelope H. Greco
Regulatory Submissions Manager
16 Electronics Avenue
Danvers, MA 01923

Re: K033305
Trade Name: INFINITY MultiView WorkStation & Telemetry System with VF4 Modifications
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: DSI
Dated: October 13, 2003
Received: October 14, 2003

Dear Ms. Greco:

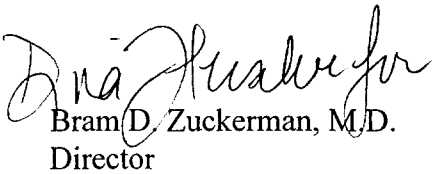
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Infinity MultiView WorkStation & Telemetry System with VF4 Modifications

Indications for Use:

The INFINITY MultiView WorkStation, INFINITY Network and Remote Display are indicated for use as a central monitoring device, communications network, and remote display for Draeger Patient Monitoring Systems and recorders.

The INFINITY MultiView WorkStation with Rest ECG is intended to provide interpretive diagnostic statements and reports when connected to an ECG monitor.

Use of the INFINITY MultiView WorkStation Telemetry System is indicated for adult and pediatric patient populations in an environment where patient care is provided by Healthcare Professionals (Physicians, Nurses, Technicians) when the professional determines that a device is required to measure and produce visual and audible alarms for any one or more of the following parameters:

- Heart rate
- ECG Arrhythmia Analysis
- Arterial oxygen saturation
- Pulse rate
- ST segment analysis

The INFINITY MultiView WorkStation (MVWS) Telemetry System with TruST is indicated for use when 12-Lead ECG monitoring with a reduced set of electrodes is desired. Reconstructed leads are intended for real-time assessment of ST segment changes.

MRI Compatibility Statement:

The Infinity MultiView WorkStation & Telemetry Systems are not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Device

(Optional Format 1-2-96)

510(k) Number K033305